

Passive Disinfection Product Effectiveness Study

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BACKGROUND

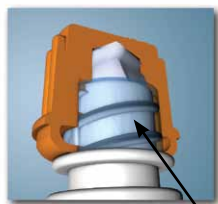
Adequate disinfection of needleless connectors is an extremely important process in protecting the patient's vascular access device. Numerous published studies have reported increased infection rates with the use of certain needleless connectors.¹⁻⁵ Karchmer reported that ~31% of nurses did not disinfect the needleless connector prior to use.⁶ Through numerous focus groups and literature review of studies that have included details of the disinfection step, many different cleaning protocols and procedures can be identified with tremendous variation between nurses and healthcare settings. At present, there are no established guidelines or recommendations for how this disinfection step should be performed.

1. Maragakis LL, Bradley KL, Song X, et al. *Increased catheter-related bloodstream infection rates after the introduction of a new mechanical valve intravenous access port.* Infect Control Hosp Epidemiol. Jan 2006;27(1):67-70.
2. Field K, McFarlane C, Cheng A, et al. *Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit.* Infect Control Hosp Epidemiol. 2007;28(5):610-613.
3. Salgado C, Chinnes L, Paczesny T, Canteo R. *Increased rate of catheter-related bloodstream infection associated with use of a needleless mechanical valve device at a long-term acute care hospital.* Infect Control Hosp Epidemiol. 2007;28(6):684-688.
4. Rupp M, Sholtz L, Jourdan D, et al. *Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve.* Clinical Infectious Diseases. 2007;44(11):1408-1414.
5. Jarvis W, Murphy C, Hall K, et al. *Health Care Associated Bloodstream Infections Associated with Negative or Positive Pressure or Displacement Mechanical Valve Needleless Connectors.* Clinical Infectious Diseases. 2009;49:000-000.
6. Karchmer T, Cook E, Palavecino E, Ohl C, Sheretz R. *Needleless valve ports may be associated with a high rate of catheter-related bloodstream infection.* Paper presented at: Society for Healthcare Epidemiology of America, 2005; Los Angeles, CA.

OBJECTIVE

To evaluate the effectiveness of SwabCap® Luer Access Valve Disinfection Cap, a passive protective cap, when used in between line accesses to disinfect a swabbable mechanical valve needleless connector.

PRODUCT DESCRIPTION



SwabCap, packaged in a sterile plastic holder, contains a pad that is saturated with 70% isopropyl alcohol. When the protective cap is connected to a mechanical valve, a minimal amount of friction is created to the top of the mechanical valve as the pad is compressed. Alcohol is released, bathing the top and threads of the valve. The patent-pending *thread cover* design is not an airtight seal but is tight enough to ensure saturation on the focused areas for disinfection—valve top and threads.

MATERIALS

- Needleless connector sample population
- Five valves of each type were studied for each organism tested – Total of 120 units tested
 - UltraSite® (B Braun Medical) ClearLink (Baxter)
 - MicroClave® (ICU Medical) MaxPlus (Maximus Medical)
 - SmartSite® positive bolus (CareFusion)
 - Posiflow™ (BD Medical)
- 3 valves from each manufacturer were used for the negative control units without inoculation (total of 18 control units)

PROCESS

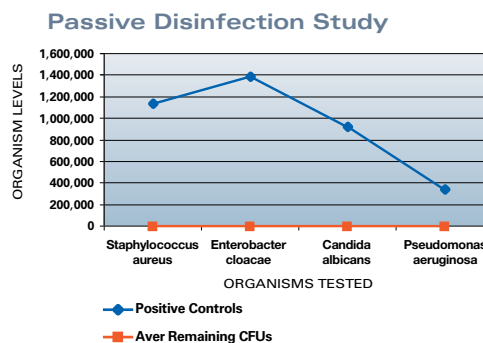
Each connector was sterilized prior to being opened. Upon opening, each connector was transferred to the stainless steel sterile racks using sterile instruments. After vortexing, 0.01 to 0.03 mL of culture medium was transferred onto each connector. Each connector was allowed 30–40 minutes for adsorption of the inoculum within a HEPA-filtered hood. Following adsorption, SwabCap was then aseptically screwed onto each connector and left for 5 minutes. SwabCap was aseptically removed, the connector transferred to a neutralizer broth, and shaken for 1 minute. Extract samples were plated in triplicate along with the final aliquot filtered through a 0.45 micron membrane. Bacterial samples were incubated at 30 to 35 degrees C for 2 to 4 days. Yeast samples were incubated at 20 to 25 degrees C for 3 to 5 days.

Organisms tested

- Staphylococcus Aureus
- Enterobacter Cloacae
- Pseudomonas Aeruginosa
- Candida Albicans

RESULTS

Zero (0) colony-forming units (cfu) counts on 109 of 120 connectors
Maximum detection of 5 cfu on the remaining 11 connectors.



CONCLUSION

- Results of this study show that Passive (non-scrubbing) Disinfection is achievable on the needleless connectors and organisms tested after five minutes of connection time.
- SwabCap use in-between line access will
 - provide protection from touch and airborne contamination
 - passively disinfect the connection surface and threads of swabbable luer access needleless connectors.
 - may help reduce intraluminal catheter colonization.

References: See above list under Background.